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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,925	04/12/2007	Paul Hadvary	25063-0002	8186

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WASHINGTON, DC 20004

EXAMINER
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LIU, CHU CHUAN

ART UNIT	PAPER NUMBER
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3777

NOTIFICATION DATE	DELIVERY MODE
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08/09/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hoganlovells.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/586,925	<b>Applicant(s)</b> HADVARY ET AL.	
	<b>Examiner</b> CHU CHUAN (JJ) LIU	<b>Art Unit</b> 3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 26-27 is/are rejected.
- 7) ☒ Claim(s) 3-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/24/2006</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1, 15 and 16 are amended. Claims 1-27 are pending for examination.

#### ***Claim Objections***

2. Claims 1-27 are objected to because of the following informalities: In regard to claims 1-27, each claim should end with a period. See MPEP 608.01(m). Appropriate correction is required.
3. Claims 3-27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 2 recites the limitation "control and measuring means" in line 1 of claim 2. There is insufficient antecedent basis for this limitation in the claim. Examiner interprets the limitation as "a control and measuring means" for the purpose of examination.
6. Claims 26 and 27 provides for the use of the device of claims 1-20, where the claim recites "device for the in-vivo measurement of the concentration of an analyte in a

Art Unit: 3777

body fluid.”, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 26 and 27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Palmer (USPN 6,537,242).

9. In regards to claim 1, Palmer discloses a device (Fig. 9) for the in-vivo measurement of the concentration of an analyte in a body fluid (abstract and Col 9 lines 30-38) comprising a) comprising:

a. a component with a flexible surface (elements 62 and 66, Fig. 9),

Art Unit: 3777

- b. means for securing adherence of that surface to the skin (element 62, Fig. 9 and Col 8 lines 52-62),
  - c. a rigid part holding one or more subcutaneously implantable sensors (elements 30' and 34, Fig. 9),
  - d. means (elements 62 and 66, Fig. 9) to position the flexible surface relative to the sensors in such a way that in a first position the sensors are concealed by the surface (Fig. 9) and in a second position the implantable parts of the sensors are exposed above the surface dashed lines, Fig. 9), and
  - e. a mechanism (needles 43, Fig. 9) to deform the surface to a convex shape and to bend it from one to the other position (convex shapes between needles, Fig. 9).
10. In regard to claim 2, Palmer discloses a control and measuring means is integrated (monitoring device 94, Fig. 11).
9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by DeMarzo (USPN 4,953,552).
10. In regard to claim 1, DeMarzo discloses a device for the in-vivo measurement of the concentration of an analyte in a body fluid (glucose, abstract) comprising a) a component with a flexible surface (elements 14 and 38, Figs. 1-4 and Col 3 lines 4-12), b) means for securing adherence of that surface to the skin (element 36, Figs. 3 and 4), c) a rigid part holding one or more subcutaneously implantable sensors (elements 18, 19, and 64, Fig. 4), d) means (element 38, Fig. 4) to position the flexible surface relative

Art Unit: 3777

to the sensors in such a way that in a first position the sensors are concealed by the surface (needle tip 60 is sealed by element 38, Fig. 4) and in a second position the implantable parts of the sensors (needle tip 64, Fig. 4) are exposed above the surface (element 38 is removed and the needle is inserted into the skin, Fig. 4), and e) a mechanism (element 58, Fig. 4) to deform the surface to a convex shape and to bend it from one to the other position (when the needle sensor is pressed into the skin, element 58 of Fig. 4 will deform the surface of the skin to a curved shape).

In regard to claim 2, DeMarzo discloses a control and measuring means are integrated (microprocessing unit 24, Fig. 1).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Swayze et al. (USPN 6,058,321) teaches a blood PH monitoring device with needle and two positions (Figs. 7-9). Lubber et al. (USPN 5,353,792) teaches a sensing device with the use of a needle sensor. Haar et al. (USPN 6,584,335) teaches a sensing probe with a needle sensor. Erickson et al. (USPN 5,746,217) teaches a device with the use of a needle sensor and a vacuum to measure constituents in body fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~4:30pm.

Art Unit: 3777

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chu Chuan Liu/  
Examiner, Art Unit 3777

/Tse Chen/  
Supervisory Patent Examiner, Art Unit 3777